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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,176	12/13/2000	Josef V. Koblisch	15916-279	8413

7590 06/18/2002

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/737,176

Applicant(s)

KOBlish ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 29-32, 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

***Election/Restrictions***

Claims 29-32, 34 and 35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims lack proper antecedent basis for "the distally facing energy transmission region". Claim 19 depends from claim 14 which fails to set forth proper antecedent basis. Further, claim 19 is essentially a duplicate of claims 6 and/or 7. It appears that claim 19 should depend from claim 18.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Deslauriers et al ('678).

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Deslauriers et al disclose a device which comprises a relatively short shaft (32) made of a malleable material. An inflatable element (10) is associated with the distal end of the shaft (via introducer tube 30). The introducer tube is provided in a desired configuration by providing the malleable introducer (32) with the appropriate shape, and the balloon (10) is used for mapping procedures.

Claims 1, 2, 5-11, 15, 17-20 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Swanson et al ('513).

Swanson et al provide a device which comprises a relatively short shaft (12) which includes an inflatable therapeutic element (20) attached to the distal end of the shaft. The inflatable element includes a porous surface (abstract) and a variety of energy emitting surfaces which may be arranged on the inflatable element (Figures 11 and 12). The emitting surfaces may include annular portions facing distally, and a plurality of conductive segments separated by non-conductive segments. With regard to claims 19 and 20, it is assumed that these claims should depend from claim 18 which provides proper antecedent basis for the elements. The prior art is applied under this assumption.

Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Debbas ('463).

The Debbas device comprises a hollow needle (60), and a therapeutic assembly located in the hollow needle and movable relative thereto. The therapeutic assembly

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includes a relatively short shaft (64) with an inflatable therapeutic element (66) attached to the distal end of the shaft.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 4 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al ('513) in view of the teaching of Lundquist ('923).

Swanson et al fail to disclose a shaft (i.e. catheter) which is malleable.

Lundquist disclose a very similar catheter system which includes a steering mechanism very much like the one used in Swanson et al. See Figure 1 of Swanson et al and Figure 1 of Lundquist for comparison. Lundquist further teach that it is known to provide such a steerable catheter system with a malleable section to allow for precurving a portion of the catheter prior to introduction into the body. See column 24, lines 1-30. Lundquist further disclose catheter sections which are more flexible at the distal section, and more rigid at the proximal section.

To have provided the Swanson et al catheter with a malleable section for controlling the shape of the catheter would have been an obvious modification for one of ordinary skill in the art in view of the Lundquist catheter system.

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Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al ('513) in view of the teaching of Abele et al ('311).

Abele et al disclose a balloon catheter device for heating tissues similar to the Swanson et al device. Swanson et al fails to specifically disclose the use of a pressure sensor to monitor the pressure of the inflatable element and to control the delivery of fluid accordingly.

Abele et al disclose the use of a pressure transducer (9) for monitoring pressure in the balloon and controlling the operation of the pump (i.e. syringe) to provide the necessary flow of fluid.

To have provided the Swanson et al system with a pressure sensor feedback system to control the delivery of fluid to the balloon based on sensed pressure would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Abele et al ('311).

Claims 1-5, 11-17 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards ('349) in view of the teaching of Gough et al ('484).

Edwards discloses an RF treatment system which includes a relatively short, malleable shaft (14), and a plurality of needle electrodes (12) which are extendable from the shaft. The needle electrodes are hollow for the delivery of a treatment fluid to tissue during delivery of RF energy (col. 4, lines 55-63). However, Edwards fails to disclose an inflatable element associated with the needle for the delivery of fluid to tissue via the balloon.

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Gough et al disclose a similar instrument which includes a plurality of needles introduced into tissue to treat tissue with RF energy. The electrodes, like the Edwards electrodes, are hollow for the delivery of fluid to tissue during treatment. Alternatively, Gough et al teach that the individual electrodes may be provided with a porous inflatable element (23) to assist in delivering the fluid to tissue being treated with the needle electrodes.

To have provided the Edwards needle electrodes with an inflatable fluid delivery member around the electrodes to enhance fluid delivery and RF treatment of tissue would have been an obvious design modification for one of ordinary skill in the art, particularly since Gough et al teach that it is known to provide needle electrodes with inflatable fluid delivery members to assist in RF treatment of tissue.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mulier et al ('395) disclose an RF needle electrode device which includes an inflatable member on the electrode. Qian ('028), Pomeranz et al ('482) and Edwards ('730) all disclose porous balloons for use in the delivery of RF energy to tissue.

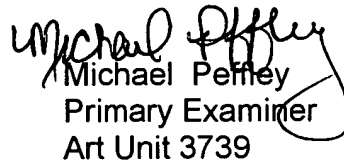
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

  
Michael Perley  
Primary Examiner  
Art Unit 3739

mp  
June 12, 2002